IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

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| SANOFI and SANOFI-AVENTIS U.S. LLC,<br><br>Plaintiffs,<br><br>v.<br><br>GLENMARK PHARMACEUTICALS INC, et al.,<br><br>Defendants. | Civil Action No. 14-264-RGA |

MEMORANDUM OPINION

Jack B. Blumenfeld, Esq., Derek J. Fahnestock, Esq., Morris, Nichols, Arsht & Tunnell LLP, Wilmington, DE; William E. Solander, Esq. (argued), Daniel J. Minion, Esq. (argued), James R. Tyminski, Esq., Fitzpatrick, Cella, Harper & Scinto, New York, NY, attorneys for Plaintiffs.

Dominick T. Gattuso, Esq., Proctor Heyman Enerio LLP, Wilmington, DE; Natalie C. Clayton, Esq., Christopher L. McArdle, Esq., Alston & Bird LLP, New York, NY, attorneys for Defendant Watson Laboratories, Inc.

John M. Seaman, Esq., Abrams & Bayliss LLP, Wilmington, DE; Maureen L. Rurka, Esq. (argued), Julia M. Johnson, Esq., Winston & Strawn LLP, Chicago, IL, attorneys for Defendant/Counterclaim-Plaintiff Sandoz Inc.

Kenneth L. Dorsney, Esq., Morris James LLP, Wilmington, DE; Neal DeYoung, Esq., H. Rajan Sharma, Esq., David J. Galluzzo, Esq. (argued), Sharma & DeYoung LLP, New York, NY, attorneys for Defendant First Time US Generics LLC.

John C. Phillips, Jr., Esq., David A. Bilson, Esq., Megan C. Haney, Esq., Phillips, Goldman & Spence, P.A., Wilmington, DE; Jeffer Ali, Esq. (argued), Sarah M. Stensland, Esq., Jennell C. Bilek, Esq., Carlson, Caspers, Vandenburgh, Lindquist & Schuman, P.A., Minneapolis, MN, attorneys for Defendants Glenmark Pharmaceuticals Inc., USA and Glenmark Pharmaceuticals Ltd.

Adam W. Poff, Esq., Michele Sherretta Budicak, Esq., Young Conaway Straight & Taylor, LLP, Wilmington, DE; Christopher J. Sorenson, Esq., Rachel C. Hughey, Esq., Aaron M. Johnson, Esq., Merchant & Gould PC, Minneapolis, MN; B. Jefferson Boggs, Jr., Esq., Matthew L.

Fedowitz, Esq., Merchant & Gould PC, Alexandria, VA, attorneys for Defendant Alembic Pharmaceuticals Limited.

Richard D. Kirk, Esq., Stephen B. Brauerman, Esq., Vanessa R. Tiradentes, Esq., Sara E. Bussiere, Esq., Bayard, P.A., Wilmington, DE; William A. Rakoczy, Esq., Paul J. Molino, Esq., John D. Polivick, Esq., Matthew V. Anderson, Esq., Patrick C. Kilgore, Esq., Rakoczy Molino Mazzochi Siwik LLP, Chicago, IL, attorneys for Defendants/Counterclaim Plaintiffs Sun Pharma Global FZE and Sun Pharmaceutical Industries, Ltd.

Brian E. Farnan, Esq., Farnan LLP, Wilmington, DE; Imron T. Aly, Esq., Joel M. Wallace, Esq., Schiff Hardin LLP, Chicago, IL; Gina M. Bassi, Esq., Schiff Hardin LLP, New York, NY, attorneys for Defendant Alkem Laboratories, Ltd.

August 28, 2015

**ANDREWS, U.S. DISTRICT JUDGE:**

Presently before the Court is the issue of claim construction of multiple terms in U.S. Patent Nos. 8,318,800 ("the '800 patent"), 7,323,493 ("the '493 patent"), and 8,410,167 ("the '167 patent"). The Court has considered the Parties' Joint Claim Construction Brief. (D.I. 194). The Court heard oral argument on August 19, 2015. (D.I. 203 [hereinafter, "Tr."]).

## I. BACKGROUND

On February 26, 2014, Plaintiffs brought this patent infringement action alleging infringement of the '800, '493, '167 patents. (D.I. 1). The '800 patent is a continuation of the '493 patent, and they share an essentially identical specification. (D.I. 194 at p. 1). Both patents are addressed to pharmaceutical compositions with dronedarone or amiodarone as the active ingredient. (*Id.* at p. 2). The '167 patent is directed to methods of using dronedarone for the prevention of cardiovascular hospitalization or mortality. (*Id.*).

## II. LEGAL STANDARD

"It is a bedrock principle of patent law that the claims of a patent define the invention to which the patentee is entitled the right to exclude." *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312 (Fed. Cir. 2005) (en banc) (internal quotation marks omitted). "'[T]here is no magic formula or catechism for conducting claim construction.' Instead, the court is free to attach the appropriate weight to appropriate sources 'in light of the statutes and policies that inform patent law.'" *SoftView LLC v. Apple Inc.*, 2013 WL 4758195, at *1 (D. Del. Sept. 4, 2013) (quoting *Phillips*, 415 F.3d at 1324). When construing patent claims, a matter of law, a court considers the literal language of the claim, the patent specification, and the prosecution history. *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 977–80 (Fed. Cir. 1995) (en banc), *aff'd*, 517 U.S. 370 (1996). Of these sources, "the specification is always highly relevant to the claim construction

analysis. Usually, it is dispositive; it is the single best guide to the meaning of a disputed term." *Phillips*, 415 F.3d at 1315 (internal quotation marks and citations omitted).

"[T]he words of a claim are generally given their ordinary and customary meaning. . . . [Which is] the meaning that the term would have to a person of ordinary skill in the art in question at the time of the invention, i.e., as of the effective filing date of the patent application." *Phillips*, 415 F.3d at 1312–13 (internal quotation marks and citations omitted). "[T]he ordinary meaning of a claim term is its meaning to [an] ordinary artisan after reading the entire patent." *Id.* at 1321 (internal quotation marks omitted). "In some cases, the ordinary meaning of claim language as understood by a person of skill in the art may be readily apparent even to lay judges, and claim construction in such cases involves little more than the application of the widely accepted meaning of commonly understood words." *Id.* at 1314 (internal citations omitted).

A court may consider extrinsic evidence, which "consists of all evidence external to the patent and prosecution history, including expert and inventor testimony, dictionaries, and learned treatises," in order to assist the court in understanding the underlying technology, the meaning of terms to one skilled in the art, and how the invention works. *Id.* at 1317–19 (internal quotation marks and citations omitted). Extrinsic evidence, however, is less reliable and less useful in claim construction than the patent and its prosecution history. *Id.*

"A claim construction is persuasive, not because it follows a certain rule, but because it defines terms in the context of the whole patent." *Renishaw PLC v. Marposs Societa' per Azioni*, 158 F.3d 1243, 1250 (Fed. Cir. 1998). It follows that "a claim interpretation that would exclude the inventor's device is rarely the correct interpretation." *Osram GmbH v. Int'l Trade Comm'n*, 505 F.3d 1351, 1358 (Fed. Cir. 2007) (internal quotation marks and citation omitted).

**IV. PATENTS AT ISSUE**

Claim 1 of the '800 patent is representative of the asserted claims in the '800 and '493 patents. It reads:

> 1. A solid pharmaceutical composition for oral administration comprising dronedarone, or a pharmaceutically acceptable salt thereof, as an active principle, and a pharmaceutically acceptable nonionic hydrophilic surfactant optionally in combination with one or more pharmaceutical excipients wherein the nonionic hydrophilic surfactant is present in a proportion of from 1% to 50% by weight of the active principle in base form.

('800 patent, col. 10, ll. 39-46).

Claims 1 and 8 are representative of the asserted claims in the '167 patent. They read:

> 1. A method of decreasing a risk of cardiovascular hospitalization in a patient, said method comprising administering to said patient an effective amount of dronedarone or a pharmaceutically acceptable salt thereof, twice a day with a morning and an evening meal, wherein said patient does not have severe heart failure, (i) wherein severe heart failure is indicated by: a) NYHA Class IV heart failure or b) hospitalization for heart failure within the last month; and (ii) wherein said patient has a history of, or current, paroxysmal or persistent non-permanent atrial fibrillation or flutter; and (iii) wherein the patient has at least one cardiovascular risk factor selected from the group consisting of:
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> i. an age greater than or equal to 75;
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> ii. hypertension;
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> iii. diabetes;
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> iv. a history of cerebral stroke or of systemic embolism;
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> v. a left atrial diameter greater than or equal to 50 mm; and
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> vi. a left ventricular ejection fraction less than 40%.
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> 8. A method of decreasing a risk of hospitalization for atrial fibrillation in a patient having a history of atrial fibrillation or atrial flutter, said method comprising administering dronedarone, or a pharmaceutically acceptable salt thereof, twice a day with a morning and an evening meal to a patient in need thereof, wherein said patient does not have severe heart failure, (i) wherein severe heart failure is indicated by: a) NYHA Class IV heart failure or b) hospitalization for heart failure within the last month, and (ii) wherein said atrial fibrillation or flutter is non-permanent and is paroxysmal or persistent; and (iii) wherein the patient has at least one cardiovascular risk factor selected from the group consisting of:
>
> i. an age greater than or equal to 75;
>
> ii. hypertension;

iii. diabetes;

iv. a history of cerebral stroke or of systemic embolism;

v. a left atrial diameter greater than or equal to 50 mm; and

vi. a left ventricular ejection fraction less than 40%

('167 patent, col. 28, l. 65-col. 29, l. 15; '167 patent, col. 29, l. 48-col. 30, l. 12).

## IV. CONSTRUCTION OF DISPUTED TERMS

1. "solid pharmaceutical composition"

   a. *Plaintiffs' proposed construction*: a pharmaceutical composition comprising ingredients which, when combined prior to formulation, are essentially in powdered form.

   b. *Defendants' proposed construction*: a pharmaceutical composition formed entirely of pulverulent solid ingredients which can be tabletted at room temperature, comprising the active principle and the excipients, these ingredients being essentially in powder form, and excluding substances in pasty or waxy form when they are brought to moderate temperature (<70° C.)

   c. *Court's construction*: a pharmaceutical composition which, at the time of tableting, is formed entirely of pulverulent solid ingredients that are essentially in powder form

The dispute with respect to this term boils down to timing. Both parties agree that, at the time the pills are tableted, all of the ingredients are powdered solids. They disagree about whether the ingredients must start out as powdered solids in their raw form. The specification sets out a definition of "solid pharmaceutical composition":

> Similarly, the expression "solid pharmaceutical composition" is understood to refer essentially to a pharmaceutical composition formed entirely of pulverulent solid ingredients which can be tabletted at room temperature, comprising the active principle and the excipients, these ingredients being essentially in powder form.
>
> Consequently, the so-called semi-solid pharmaceutical compositions, formed of substances in pasty or waxy form when they are brought to moderate temperature (<70° C.), do not form part of the invention.

('800 patent, col. 1, ll. 34-43). The inventors were their own lexicographers for "solid pharmaceutical composition." Unfortunately, their lexicography could have been more precise. Both parties agree that the term requires some construction. (Tr. 60).

Plaintiffs argue that the definition requires the ingredients to be solid just before tableting. (*Id.* at 40). They maintain that the definition in the specification does not exclude ingredients that are liquid in their raw form. (*Id.*). Plaintiffs note that the specification discloses many nonionic hydrophilic surfactants that are not powders at room temperature. (D.I. 194 at p. 4). In particular, Plaintiffs note that Defendants' construction would read out the preferred embodiment, poloxamer 407. (*Id.* at p. 5). In addition, Plaintiffs argue that dependent claims recite nonionic hydrophilic surfactants that are not powders in their raw form. (*Id.*). Plaintiffs contend that those claims would be rendered meaningless if Defendants' construction were adopted. (*Id.*).

Defendants argue that when a specification provides a definition for a term, that definition governs. (*Id.* at p. 9 (citing *Phillips*, 415 F.3d at 1316)). Defendants maintain that their construction nearly identically tracks the specification, with only minor adjustments for clarity. (*Id.*). Defendants do not dispute that the specification discloses surfactants that do not fit in their proposed construction. (*Id.* at p. 11). Defendants assert that the subject matter disclosed in a patent can be broader than what is claimed, and the disclosure of those surfactants is therefore not relevant. Defendants further argue that any dependent claims that include liquid nonionic hydrophilic surfactants are indefinite. (*Id.* at p. 12).

I agree with Plaintiffs that the ingredients do not need to be powdered solids at all times. Rather, the ingredients must be powdered solids when they are tableted at room temperature. Defendants are correct that when a term is defined in the specification, that definition governs.

The definition, however, must be understood in the context of the patent as a whole. The preferred embodiment and dependent claims recite ingredients that are, at some point in the production process, not powdered solids. The Federal Circuit has explained that "a claim interpretation that excludes a preferred embodiment from the scope of the claim is rarely, if ever, correct." *On-Line Tech. v. Bodenseewerk Perkin-Elmer*, 386 F.3d 1133, 1138 (Fed. Cir. 2004). The definition refers to the state of the ingredients in the context of tableting. It does not indicate that the ingredients must be powdered solids at all times. I therefore do not think that Plaintiffs' interpretation is inconsistent with the definition in the specification.

I do not think that the second sentence in the definition is helpful or provides clarity. Both parties agree that it is confusing. (Tr. 50, 55). I will therefore not include it in the construction.

Although I agree with Plaintiffs' argument generally, I do not think their proposed construction captures the proper understanding of the term. Including "comprising" allows for other, unspecified ingredients to be present. A composition with liquid ingredients at the time of tableting would therefore fit within Plaintiffs' proposed construction. That is not in keeping with the definition, which states that the composition is "formed entirely of pulverulent solid ingredients." ('800 patent, col. 1, l. 36). I will therefore construe "solid pharmaceutical composition" as "a pharmaceutical composition which, at the time of tableting, is formed entirely of pulverulent solid ingredients that are essentially in powder form."

2. "nonionic hydrophilic surfactant"

   a. *Plaintiffs' proposed construction*: plain and ordinary meaning

   b. *Defendants' proposed construction*: a nonionic hydrophilic surfactant which is not a polysorbate surfactant

   c. *Court's construction*: nonionic hydrophilic surfactant which is not a polysorbate surfactant

The only issue with respect to this term is whether polysorbate surfactants are excluded from nonionic hydrophilic surfactants. The parties do not dispute that, as a matter of chemistry, a polysorbate surfactant is a nonionic hydrophilic surfactant. (D.I. 194 at pp. 35, 39). Defendants argue that the applicants disclaimed polysorbate surfactants while prosecuting the '493 patent. (*Id.* at p. 25). Defendants contend that the disclaimer also applies to the '800 patent, which is a continuation of the '493 patent. (*Id.*). Defendants maintain that in order to recapture disclaimed subject matter, an applicant must clearly inform the examiner of the applicant's intent to do so. (*Id.* at pp. 24-25).

Plaintiffs argue that the examiner of the '800 patent understood polysorbate surfactants to be included in the claim scope. (Tr. 21). Plaintiffs contend that because the relevant prior art was considered and polysorbate surfactants were specifically addressed, everyone was on notice that the applicants were reclaiming polysorbate surfactants. (D.I. 194 at pp. 38-39).

I agree with Defendants. The'493 patent applicants amended the claims to explicitly exclude polysorbate surfactants in order to overcome a prior art rejection. I think that in order to properly recapture the disclaimed subject matter, the '800 applicants needed to clearly indicate their intent to do so. It is not enough that the examiner considered polysorbate surfactants. The examiner should have been made aware that polysorbate surfactants were previously excluded to overcome a rejection, and that the applicants intended the new claim to recapture them.

I will therefore construe "nonionic hydrophilic surfactant" as "nonionic hydrophilic surfactant which is not a polysorbate surfactant."

3. "a method of decreasing a risk of cardiovascular hospitalization in a patient"; "a method of decreasing a risk of hospitalization for atrial fibrillation in a patient having a history of atrial fibrillation or atrial flutter"

   a. *Plaintiffs' proposed construction*: limiting preamble

b. *Defendants' proposed construction*: non-limiting preamble

c. *Court's construction*: limiting preamble

The dispute with respect to these terms is whether the preambles of claims 1 and 8 of the '167 patent are limiting. Plaintiffs argue that they are limiting because they serve as an antecedent basis to terms in the claims at issue and other dependent claims. (Tr. 97-98). In addition, Plaintiffs argue that the preambles are necessary to give life and vitality to what an "effective amount" of dronedarone is. (*Id.* at 98-99). Plaintiffs also argue that the applicants relied on the preambles as a key feature of the claims in the prosecution history. (*Id.* at 95-96). Defendants respond that the preambles are not limiting, but rather an intended use of the method. (D.I. 194 at p. 70). They argue that the preamble does not serve as an antecedent basis for "effective amount, "said patient," or "a patient in need thereof" because those terms are understood without reference to the preamble. (*Id.* at pp. 72-13).

I find that the preambles are limiting. Claim 1 recites: "A method of decreasing a risk of cardiovascular hospitalization in a patient, said method comprising administering to said patient an effective amount of dronedarone . . . ." ('167 patent, col. 28, ll. 65-67). I agree with Plaintiffs that the preamble is necessary to give meaning to what constitutes an "effective amount" of dronedarone. Similarly, the preamble of claim 8 gives life and meaning to "a patient in need thereof" in the body of the claim. In addition, the preamble of claim 1 serves as an antecedent basis for "said cardiovascular hospitalization" in dependent claim 2. With respect to claim 8, the preamble serves as an antecedent basis for "said atrial fibrillation or atrial flutter" in the body of the claim.

4. "effective amount"

a. *Plaintiffs' proposed construction*: an amount effective to decrease a risk of cardiovascular hospitalization

b. *Defendants' proposed construction*: plain and ordinary meaning

c. *Court's construction*: an amount effective to decrease a risk of cardiovascular hospitalization

Consistent with the foregoing analysis, I find that "effective amount" means "an amount effective to decrease a risk of cardiovascular hospitalization." "Effective amount" has a customary usage: the amount that is effective to accomplish the purpose of the claim. *Abbott Labs. v. Baxter Pharm. Products, Inc.*, 334 F.3d 1274, 1277-78 (Fed. Cir. 2003). In this case, the claim is addressed to decreasing a risk of cardiovascular hospitalization. The proper construction of "effective amount" is therefore the amount that achieves that goal.

5. "to a patient in need thereof"

a. *Plaintiffs' proposed construction*: to a patient with a history of atrial fibrillation or flutter with the intent of decreasing risk of hospitalization for atrial fibrillation

b. *Defendants' proposed construction*: plain and ordinary meaning

c. *Court's construction*: to a patient with a history of atrial fibrillation or flutter with the intent of decreasing risk of hospitalization for atrial fibrillation

The dispute with respect to this term is whether there is an intent limitation such that the dronedarone must be administered to a patient with a known history of atrial fibrillation or flutter with the intent of decreasing the risk of hospitalization. Plaintiffs rely on *Jansen v. Rexall Sundown, Inc.* to argue that there is an intent requirement. 342 F.3d 1329, 1333 (Fed. Cir. 2003). I agree that *Jansen* is on point. In that case, the court held that where the preamble sets forth an intended effect and the body of the claim directs that the method be performed to a patient "in need thereof," the phrase "in need thereof" "gives life and meaning to the preamble['s] statement of purpose." (*Id.* at 1332-33). In that situation, the preamble is a "statement of the intentional

purpose for which the method must be performed." (*Id.*). Here, as in *Jansen*, the combination of a limiting preamble and the recitation of a patient "in need thereof" adds an intent limitation.

6. "prevents"

a. *Plaintiffs' proposed construction*: reduces

b. *Defendants' proposed construction*: plain and ordinary meaning

c. *Court's construction*: plain and ordinary meaning

At oral argument, Plaintiffs agreed to adopt the plain and ordinary meaning of "prevents" as used in the medical field. (Tr. 132). I agree that the plain and ordinary meaning applies. As stated at oral argument, I do not understand "prevent" in this context to mean completely eliminate. (*Id.*).

## V. CONCLUSION

Within five days the parties shall submit a proposed order consistent with this Memorandum Opinion.